

REMARKS

Entry of the above amendment will effect replacement of all previously pending claims with new claims 59-89. These new claims add no new matter and are fully supported by the specification and claims as originally filed. Specifically, new claims 59 and 84 are now directed to methods for introducing an agent into cells of a tissue by applying a voltage pulse between a plurality of opposing pairs of needle electrodes disposed in the tissue to be treated. Support for opposing pairs of electrode needles may be found in the specification in paragraphs 0047, 0049, and 0052. One or more electric field(s) is established between the pair(s) of needle electrodes. It is to be noted that said electric fields may be of different strengths and durations that are applied simultaneously or at different times depending, for example, on electrode spacing (e.g., each pair of electrodes may be differently spaced), the level of voltage applied in a given pulse (or series of pulses), etc.

New claim 89 is directed to a two-step method of introducing agents into cells involving electroporation. One step involves the introduction of a therapeutic agent into the tissue to be treated and the other step involves the use of an electrode apparatus to effect electroporation. As specified, the electroporation apparatus comprises a support member having disposed thereon two or more opposing pairs of needle electrodes arranged relative to one another to form an electrode array. Support for this sort of device is found throughout the specification. For example, see Figure 2. At any given instant, some or all of the opposed pairs of needle electrodes may be energized by a power supply in electrical communication therewith.

Entry of the new claims is respectfully requested, as is their consideration in view of the following remarks.

Double Patenting

Claims 2, 3, 5-27, and 58 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. patent no. 6,233,482. Applicants respectfully request the Examiner either withdraw this rejection or hold it

in abeyance until one or more claims of the pending application is allowed, as the subject matter claimed may change during prosecution. Also, Applicants respectfully submit that the invention as now claimed is not the same invention as that claimed in the '482 patent, allowing this rejection to be withdrawn.

Rejection Under 35 U.S.C. 103

In the previous Office action claims 2, 3, 5-27, and 58 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable in view of a reference by Mir. Applicants respectfully traverse this rejection to the extent that it may be held to apply to the newly filed claims. In particular, Applicants disagree with the characterization that the Mir reference teaches all elements of the claims, especially as amended. As an initial matter, Applicants note that the Mir reference does not disclose a device that includes multiple pairs of opposed electrodes. Instead, the devices disclosed in the Mir reference contain minimally three, and at most seven, electrodes. In operation, at any given instant only two electrodes (i.e., only a single pair) of the device are powered when an electrical impulse is applied. In contrast, in the instantly claimed methods, a plurality of opposing pairs of electrodes (i.e., at least two pairs) are powered when an electrical impulse is applied.


In order to establish a *prima facie* case of obviousness over a reference, the burden is on the PTO to provide a convincing line of reasoning as to why the artisan would have made the proposed modification to the reference, a reasonable expectation of success, and the presence, explicitly or by suggestion, of all elements (or steps) of the rejected claim. See MPEP 2142, et seq. The Mir reference fails to render Applicants' invention obvious under this test. Indeed, the Mir reference does not even suggest, let alone teach, the use of two or more opposed pairs of simultaneously powered electrodes to effect electroporation. For example, the Mir reference discloses a device that comprises a central electrode with from two to six other surrounding electrodes configured in a circular array. The way the device is configured, the electric pulse applicator applies pulses between needle pairs in a sequential manner. As stated in the specification, "...it is possible to excite the different pairs of electrodes one after another...".

Column 4, lines 10-12. Hence, the Mir reference in actuality teaches away from using a plurality of opposing pairs of needle electrodes.

As the Mir reference was the only art cited in the last Office action, and since the pending claims patentably differ from that disclosure, Applicants respectfully submit that their claimed invention is both patentable and in condition for allowance. An early notice to that effect is thus earnestly requested. Should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at 858.735.7090 so that they may be promptly resolved.

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Respectfully submitted,

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